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May 4, 2004

Via Overnight Mail

Dockets Management Branch
Food and Drug Administration (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

The undersigned submits this petition in quadruplicate under Section 505(j) of the Federal Food, Drug and Cosmetic Act and 21 CFR 10.30 and 314.161, to request the Commissioner of Food and Drugs to determine that the reference listed drug ("RLD") Zithromax® (azithromycin) oral capsules, NDA 50-670, was not withdrawn from sale for reasons related to safety or effectiveness.

A. Action Requested

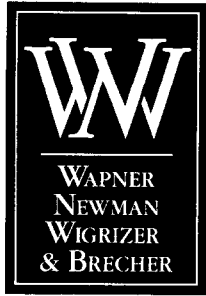
The Petitioner requests that the Commissioner of Food and Drugs makes a determination that the RLD, Pfizer's Zithromax®, azithromycin oral capsules, eq. 250 mg base, NDA 50-670, was not withdrawn from sale for reasons to safety or effectiveness.

B. Statement of Grounds

The U.S. Food and Drug Administration ("FDA") maintains a list of drug products that are eligible for submission as abbreviated new drug applications ("ANDAs"). The *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the Orange Book, contains all FDA - approved drug products. The RLD, Pfizer's Zithromax®, azithromycin oral capsules, eq. 250 mg base, NDA 50-670, was approved by FDA, but is currently listed in the discontinued section of the Orange Book.

2004 P-0220

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Under its implementing regulations at 21 CFR 314.161(a)(1), FDA must make a determination whether a discontinued listed drug was withdrawn from sale for reasons of safety or effectiveness prior to approving an ANDA that refers to that discontinued drug. Upon making a determination that such a listed drug was not withdrawn from sale for reasons of safety or effectiveness, FDA is required to publish a notice of this determination in the Federal Register. 21 CFR 314.161(e).

The Petitioner has no information or evidence concerning the reason that Pfizer discontinued selling Zithromax®, azithromycin oral capsules, eq. 250 mg base, NDA 50-670. Nevertheless, the Petitioner asserts that the discontinuation of the marketing of the product was for reasons unrelated to safety or effectiveness, based on Pfizer's continued marketing of Zithromax®, azithromycin oral capsules, in dosage strengths eq. to 250 mg and 600 mg base.

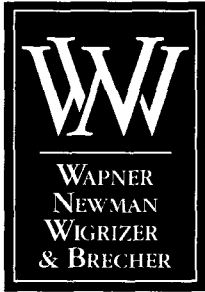
The Petitioner requests that the FDA determine that Pfizer's decision to withdraw Zithromax®, azithromycin oral capsules, eq. 250 mg base, NDA 50-670, was for reasons other than safety or effectiveness.

C. Environmental Impact

A claim for categorical exclusion of the requirement for submission of an environmental assessment is made pursuant to 21 CFR 25.31.

D. Economic Impact

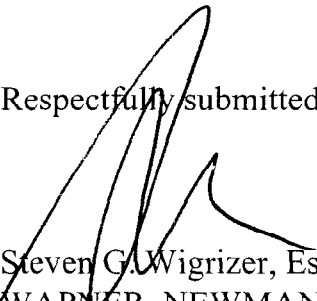
Pursuant to 21 CFR 10.30(b), economic impact information will be provided at the request of the Commissioner.



E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the Petitioner, which are unfavorable for the petition.

Respectfully submitted,



Steven G. Wigrizer, Esquire
WAPNER, NEWMAN, WIGRIZER & BRECHER

SGW/vm